

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

AMNIOTIC THERAPIES, LLC

Plaintiff

v.

UNITED STATES FOOD AND
DRUG ADMINISTRATION

Defendant

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Case No. 3:16-cv-2412

**APPENDIX IN SUPPORT OF AMNIOTIC THERAPIES, LLC'S MOTION FOR
TEMPORARY RESTRAINING ORDER AND REQUEST FOR IMMEDIATE HEARING**

Amniotic Therapies, LLC files this Appendix in Support of Emergency Motion for Temporary Restraining Order and Request for Immediate Hearing ("Motion"). The exhibits attached hereto are incorporated by reference into Amniotic Therapies, LLC's Motion and accompanying Memorandum in Support of Emergency Motion for Temporary Restraining Order.

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Respectfully submitted,

/s/ Joe Kendall

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Douglas B. Farquhar

(Motion for pro hac vice admission to be filed)

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CERTIFICATE OF SERVICE

I certify that a copy of this document was forwarded via email to Shoshana Hutchinson and Perham Gorji of the Office of Chief Counsel of the U.S. Food and Drug Administration on August 19, 2016.

/s/ Joe Kendall

JOE KENDALL

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

AMNIOTIC THERAPIES, LLC

Plaintiff,

v.

U.S. FOOD AND DRUG ADMINISTRATION,

Defendant.

Case No. 3:16-cv-2412

DECLARATION OF JENNIFER M. THOMAS

1. I, Jennifer M. Thomas, hereby submit this Declaration in support of Plaintiff Amniotic Therapies, LLC's Motion for Temporary Restraining Order. I am an Associate at Hyman, Phelps & McNamara, P.C. I make the following statements based on personal knowledge or information provided to me and on review of the records referenced and attached as exhibits to Amniotic Therapies, LLC's Appendix in support of the aforementioned Motion.

2. Exhibit 1 to the Appendix is a true and correct copy of the AlphaGEMS Instructions for Use in effect in 2015.

3. Exhibit 4 to the Appendix is a true and correct copy of the Order issued by the U.S. Food and Drug Administration ("FDA") to Amniotic Therapies, LLC, on August 16, 2016.

4. Exhibit 5 to the appendix is a true and correct copy of a Warning Letter issued by FDA to Amniotic Therapies, LLC, on August 16, 2016.

5. Exhibit 6 to the Appendix is a true and correct copy of an email exchange between Douglas B. Farquhar, Hyman, Phelps & McNamara, P.C., and Scott Kaplan, Associate Chief Counsel, in the Office of Chief Counsel, FDA from May 17-21, 2016 regarding Amniotic

Therapies' requests for documentation related to FDA or the CDC's testing of the company's products, as well as all adverse event reports received by FDA and associated with the company's products.

6. Exhibit 7 to the Appendix is a true and correct copy of a request made by Amniotic Therapies counsel Douglas B. Farquhar to FDA's Division of Freedom of Information under the Freedom of Information Act, dated July 11, 2016.

7. Exhibit 8 to the Appendix is a true and correct copy of a request made by Amniotic Therapies counsel Douglas B. Farquhar to the Centers for Disease Control Chief FOIA Officer under the Freedom of Information Act, dated July 11, 2016..

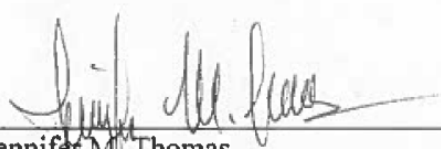
8. Exhibit 9 to the Appendix is a true and correct copy of a letter from the FDA Division of Freedom of Information responding to Amniotic Therapies counsel Douglas B. Farquhar's request under the Freedom of Information Act, dated August 10, 2016, and attachments.

9. Exhibit 10 to the Appendix is a true and correct copy of the AlphaPATCH Instructions for Use currently in effect.

I declare under penalty of perjury that the foregoing is true and correct.

8/18/2016

Date



Jennifer M. Thomas
Hymat, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005



Contents

This package contains Human Cellular and Tissue Based Products (HCT/P) as defined by US FDA 21 CFR Part 1271.

CAUTION: Federal (USA) law restricts this product to sale by or on the order of a licensed physician.

The donated human tissue has been determined eligible for human transplantation according to the criteria outlined in the Donor Selection section. AlphaGEMS is packaged in a cryo tube, inside a peel pouch in an outer box. The tissue has been tested for sterility. Included in the packaging are a Tracking Record and a set of patient labels.

Description

- AlphaGEMS is a biological wound covering derived from human amnion.
- AlphaGEMS is intended for single patient, one time use only.
- AlphaGEMS must be used immediately after opening or discarded.

Precautions

- Do not use AlphaGEMS if packaging is damaged.
- Once the outer pouch is opened, AlphaGEMS should be used as soon as possible.
- Do not sterilize, re-sterilize or autoclave product.
- As with any human tissue, the possibility of infectious agent transmission cannot be eliminated, although all screening and microbial tests were satisfactory for this donor.
- Do not use on patients with a history of drug reactions to Penicillin or Amphotericin B.

Donor Selection

The Medical Director of the recovery agency has determined that the donor of the tissue in this product is eligible to donate tissue for transplantation based on the following criteria:

- The results of the donor screening indicated that the donor was free from risk factors for and clinical evidence of infection due to relevant communicable disease agents and diseases; and
- The results of donor testing for the following relevant communicable disease agents are negative or non-reactive:
 - Human immunodeficiency virus type 1 and 2 (HIV-1 and HIV-2)
 - hepatitis B
 - hepatitis C
 - human T-lymphotropic virus type 1 and type 2 (HTLV-1 and HTLV-2)
 - syphilis
 - chlamydia

A donor's medical history and behavior risk assessment are obtained prior to donation. Discussions with physicians and/or the donor mother are conducted to identify circumstances that may lead to exclusion of the donor or donated tissue. The blood sample test results, donor medical history, behavior risk assessment, physical assessment and other records have been evaluated.

Recovery

Tissue recovery is performed by Birth Tissue Recovery, using aseptic techniques. At the time of recovery, medical records are collected and reviewed for donor eligibility.

Processing

AlphaGEMS is processed by Amniotic Therapies, Inc. HCT/Ps are processed in a controlled environment using methods designed to prevent contamination of the products. AlphaGEMS contains 10% v/v Dimethyl Sulfoxide (DMSO) as a cryoprotectant.

Storage

It is the responsibility of the end user to maintain AlphaGEMS in its original packaging at -65°C or colder until use. Product expiration is printed on the outside of the box.

Recommended Instructions

These instructions are only guidelines and are not intended to supersede protocols or professional judgment regarding patient care.

- Open box containing AlphaGEMS and remove foil package.
- Open the foil pouch outside the sterile field, remove tube and thaw before opening.
- Open the vial and present to the physician so the allograft can be drawn into a sterile syringe.
- An 18-gauge or larger needle may be used to draw up AlphaGEMS and a 21-gauge used for application.
- AlphaGEMS is now ready for use.

Tracking

Recipient record must be maintained for the purpose of tracking tissue post-transplant. The Product ID number must be recorded in the operative record. The tracing record must be completed and mailed back to Amniotic Therapies. Patient labels are included in this package to aid in tracking.

**IN THE UNITED STATES DISTRICT COURT
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AMNIOTIC THERAPIES, LLC

Plaintiff,

v.

U.S. FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No.

DECLARATION OF JASON RENEAU

1. I, Jason Reneau, hereby submit this Declaration in support of Plaintiff Amniotic Therapies, LLC's Motion for Temporary Restraining Order. I have personal knowledge of the facts set forth herein, or believe them to be true based on my experience in the medical industry or upon information provided to me by others. If asked to do so I could testify truthfully about the matters contained herein.

2. I am the Chief Operating Officer of Amniotic Therapies, LLC ("Amniotic Therapies"). I have held this position since July 22, 2013. Prior to that date, I was employed in the biotechnology industry for approximately six years.

3. Amniotic Therapies produces and distributes amniotic tissue products for use in medical settings. Amniotic Therapies' products act as wound coverings and are intended to enhance the body's ability to heal following surgery.

4. Amniotic Therapies produces three product lines, AlphaGEMS (morcelized amniotic tissue suspended in liquid), AlphaPATCH (dehydrated amniotic tissue patches), and AlphaVISION (dehydrated amniotic tissue patches and discs for use following ocular surgery).

5. Each of the products in these three lines is intended to be applied to a wound or following surgery. The products are regulated by the U.S. Food and Drug Administration (“FDA”) as human cells, tissues, or cellular or tissue-based products (“HCT/Ps”) under 21 CFR Part 1271.

6. Only Amniotic Therapies AlphaPATCH and AlphaVISION products are the subject of the FDA Order dated August 16, 2016, which is the subject of this litigation.

7. During the period from August-October 2015, four adverse reactions were reported to FDA indicating that four patients having spinal surgery during that timeframe subsequently developed infections at the site of the surgery. All four of the patients were located at St. Vincent’s Hospital in Cleveland, Ohio. We have had no other reports of patient infections from any other users of our products. To my knowledge, two of the four adverse reaction reports indicated that Amniotic Therapies AlphaGEMS product was used during the surgery. Although all four patients developed infections, it appears, from the limited information provided by FDA, that two out of the four infections were from the same organism.

8. I had several conversations with knowledgeable personnel at St. Vincent’s Hospital about the use of the AlphaGEMS product resulting in the MedWatch reports, although I did not see the MedWatch reports until this week. In those conversations, I was informed that the same surgeon had treated the four patients, and that he did not realize that the vials containing AlphaGEMS product could not be introduced into the sterile field. In fact, the Instructions for Use applicable to those products informed surgical personnel that the pouches containing the vials were supposed to be opened outside the sterile field, informing surgical personnel that they were required to withdraw the contents of the vials in a sterile syringe and

introduce that into the sterile field. The Instructions for Use are attached to Amniotic Therapies, LLC's Appendix in Support of Motion for Temporary Restraining Order as Exhibit 1.

9. On January 7 and 26, 2016 the University of Alabama issued two reports stating that two vials of AlphaGEMS products that they had received from the Centers for Disease Control and Prevention (CDC) with the lot number 150792 grew contaminants. Neither of these reports states the condition of the vials when received or from whom they were received. It is not possible to determine if the said vials of AlphaGEMS product were sent to the University of Alabama Birmingham by FDA and/or the CDC or directly from St. Vincent Charity Medical Center in Cleveland, Ohio, nor the manner in which they were transported, or the conditions in which they were held during transport, or after receipt. Nor are we aware what test methodology or test conditions were for the tests performed at the University of Alabama. Any of these factors could affect the validity of the findings reported in the test results, which are the only documents we have.

10. On February 17, 2016 Amniotic Therapies voluntarily recalled 25 amniotic membrane allografts from lot number 150792, the lot that was potentially associated with the four adverse reactions.

11. On April 29, 2016, FDA sent Amniotic Therapies a letter indicating that they agreed with our "voluntary recall of 25 amniotic membrane allografts from lot number 150792..." and further stated that "...FDA has determined that [human allografts processed in a manner that could cause contamination or cross-contamination represent] a serious health hazard, which may be life-threatening. Because of the nature of the health hazard, we are classifying this action as a Class I Recall."

12. From March 23 through May 4, 2016 FDA conducted an inspection of Amniotic Therapies establishment, and issued Amniotic Therapies a nine item Form 483 detailing its inspectional observations at the close of the inspection.

13. During FDA's inspection, I requested from the FDA inspector documentation surrounding the University of Alabama test results, as well as documentation relating to the Adverse Reaction reports associated with Amniotic Therapies' product. The FDA inspector denied this request.

14. On May 17, 2016, Douglas Farquhar, representing Amniotic Therapies, requested that FDA provide Amniotic Therapies with copies of the Adverse Reaction reports involving the four patients, as well as shipping and testing data on the vials of AlphaGEMS products that were sent to the University of Alabama at Birmingham for testing.

15. On May 19, 2016, Scott Kaplan, in the Office of Chief Counsel, FDA, advised Amniotic Therapies, through their attorney Douglas Farquhar, that FDA would not be providing the copies of the Adverse Reaction reports of the four infected patients, nor the shipping and testing data on the vials of AlphaGEMS products that had been shipped from St. Vincent Charity Medical Center. Instead, Mr. Kaplan stated that Amniotic Therapies would need to file a Freedom of Information Act ("FOIA") request with FDA for the Adverse Reaction reports and a separate FOIA request with CDC for the shipping and testing data on the vials of AlphaGEMS products that had been shipped from St. Vincent Charity Medical Center. It is my understanding that FDA provided only the MedWatch reports, on August 10, 2016, and the copies provided are nearly illegible.

16. On May 24, 2016, almost three weeks after the inspection closed, FDA issued Amniotic Therapies an amended Form 483 containing inspectional observations, after Amniotic Therapies had brought to the agency's attention certain inaccuracies with the first Form 483.

17. On June 7, 2016 Amniotic Therapies filed its response to FDA's amended Form 483, detailing the substantial remediation that Amniotic Therapies had undertaken to resolve the Form 483 inspectional observations.

18. On August 16, 2016, over three months after the inspection and over two months after receiving Amniotic Therapies' response addressing FDA's inspectional observations, FDA issued the Order that is the subject of this lawsuit.

19. I understand that, absent a grant of relief from this Court, the FDA Order at issue will require Amniotic Therapies to (1) immediately cease manufacturing, including distribution of, all products except the AlphaGEMS products; (2) destroy all its products except the AlphaGEMS products; and (3) recall and destroy all products that the company has ever distributed except the AlphaGEMS products.

20. I am aware of the considerable and irreparable harm that Amniotic Therapies will suffer absent a grant of relief by this court pending review of the FDA Order. Such harm includes, but is not limited to, significant lost profits and sales from the subject products, lost profits and sales across all its product lines, a decrease in market share, and decreased access to important customers.

21. Additionally, should the FDA Order be permitted to go into effect, the actions required by Amniotic Therapies would seriously and irreparably damage its business reputation and relationship with customers.

22. Amniotic Therapies' projected U.S. revenues for 2016 are \$1,080,000. The products subject to the FDA Order represent approximately 15% of those revenues.

23. Moreover, Amniotic Therapies estimates the value of its inventory subject to the FDA Order is approximately \$359,000 and the estimated value of the distributed product that would need to be recalled under the FDA Order is approximately \$44,000. If the FDA Order goes into effect, absent relief from this Court, it could take Amniotic Therapies up to 8 months and would cost approximately \$250,000 to build the necessary inventory before the company could again begin selling the product.

24. Many of Amniotic Therapies' customers purchase more than one category of product from the company. If Amniotic Therapies is unable to meet *all* the needs of those customers, they may seek a new supplier altogether.

25. In my experience, if Amniotic Therapies is required to recall and destroy products that it has sold to customers, the company will likely lose those customers permanently not only for the products that are recalled but for all products produced by the company. Amniotic Therapies will also be damaged by negative word-of-mouth among healthcare practitioners and from competitors regarding its products.

26. I estimate that Amniotic Therapies would suffer at least \$300,000 in lost revenues immediately upon the FDA Order going into effect, in addition to the irreparable harm to its business reputation. Amniotic Therapies would continue to lose approximately \$10,000 to \$15,000 each week that the FDA Order is in effect, and those losses would continue even if the FDA Order is subsequently lifted, as the company attempts to rebuild inventory.

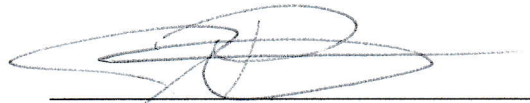
27. As a result of the aforementioned injuries, Amniotic Therapies would likely be required to lay off or at least suspend three of its five employees. The company may lose those highly skilled and trained employees permanently.

28. In short, if this Court does not grant the requested relief, and the FDA Order goes into effect, Amniotic Therapies may be forced to cease operations altogether.

I declare under penalty of perjury that the foregoing is true and correct.

8/18/2016

Date

A handwritten signature in blue ink, appearing to read 'JR', is written over a horizontal line.

Jason Reneau
Chief Operating Officer
Amniotic Therapies, LLC

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Plaintiff,

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Defendant.

Civil Action No.

DECLARATION OF NEIL RIORDAN

1. I, Neil Riordan, am the Manager of Amniotic Therapies, LLC.
2. I personally communicated by telephone on September 21, 2015, with the surgeon who used our AlphaGEMS products on patients at St. Vincent's Hospital in Cleveland, Ohio, who he reported experienced infections after surgery.
3. The surgeon informed me that his staff had introduced the vial of the AlphaGEMS product into the sterile field--in contradiction to the handling instructions.

I declare under penalty of perjury that the foregoing is true and correct.

8/18/2016

Date



Neil Riordan
Manager
Amniotic Therapies, LLC



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

ORDER TO CEASE MANUFACTURING, RECALL, AND DESTROY HCT/Ps

August 16, 2016

HAND DELIVERED

Mr. Bryant Gaines
Chief Executive Officer
Amniotic Therapies, LLC
11496 Luna Road
Suite 800
Farmers Branch, TX 75234-9417

Dear Mr. Gaines:

Your establishment, Amniotic Therapies, LLC (Amniotic Therapies or establishment), located at 11496 Luna Road, Suite 800, Farmers Branch, TX, manufactures human cells, tissues, or cellular or tissue-based products (HCT/Ps).¹ The Food and Drug Administration (FDA or Agency) conducted an inspection of your establishment between March 23 and May 4, 2016, and at the conclusion of the inspection, the FDA investigator issued you² a Form FDA-483, List of Inspectional Observations.³ Based on a review of these inspectional findings and other available information, FDA has found that there are reasonable grounds to believe that the HCT/Ps manufactured by Amniotic Therapies are violative HCT/Ps because they were manufactured in violation of Title 21, Code of Federal Regulations, Part 1271 (21 CFR 1271), issued under the authority of Section 361 of the Public Health Service Act (PHS Act) [42 United States Code (USC) 264] and, therefore, the conditions of manufacture of your HCT/Ps do not provide adequate protections against the risks of communicable disease transmission. Furthermore, FDA has determined that Amniotic Therapies is in violation of the regulations at 21 CFR 1271 and, therefore, does not provide adequate protections against the risks of communicable disease transmission. The Agency further concludes that there are reasonable grounds to believe the HCT/Ps manufactured by your establishment pose a danger to health. Accordingly, FDA issues this order to cease manufacturing, effective immediately, and

¹ This order does not apply to the following products that are manufactured by Amniotic Therapies: AlphaGEMS, AlphaGEMS Nano, and AlphaGEMS Micro. Accordingly, references in this order to HCT/Ps do not include such products. FDA intends to communicate with Amniotic Therapies separately regarding these products.

² Throughout this order, "you" refers both to the establishment, and/or you personally, as well as in your capacity as Chief Executive Officer of the establishment, as appropriate.

³ FDA issued the original Form FDA-483 on May 4, 2016, subsequently revised it, and issued an amended Form FDA-483 to you on May 24, 2016.

Mr. Bryant Gaines
Amniotic Therapies LLC

further orders the recall and destruction of HCT/Ps within five (5) working days from the date of receipt of this order, as set forth below.

Pursuant to 21 CFR 1271.440(a)(1) and (3), FDA hereby orders you to:⁴

1. Immediately cease all manufacturing of HCT/Ps until compliance with the regulations in 21 CFR 1271 has been achieved and you have been provided written authorization from FDA to resume operations. Under 21 CFR 1271.3(e), manufacture means, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor;
2. Destroy all HCT/Ps that are in your possession; and
3. Within five (5) working days from the date of receipt of this order, recall, and destroy all HCT/Ps distributed since September 11, 2014, the date you began manufacturing HCT/Ps.

Please forward your consignee/customer notification letter to FDA (contact provided below) for review and approval prior to sending to your consignees/customers.

FDA's inspection and record review revealed significant noncompliance with the relevant federal regulations, including, but not limited to, the following violations,⁵ some of which are recurring:⁶

CURRENT GOOD TISSUE PRACTICE VIOLATIONS

Process Validation

Failure to validate and approve a process according to established procedures where the results of processing cannot be fully verified by subsequent inspection and tests. The validation activities and results must be documented, including the date and signature of the individual(s) approving the validation. [21 CFR 1271.230(a)].

For example, you have failed to document adequate validation of the manufacturing processes that you perform on your HCT/Ps to ensure that contamination or cross-contamination does not occur during processing, and to ensure that processing prevents the introduction, transmission, or spread of communicable disease through the use of the HCT/P.

⁴ Neither this order, nor the observations listed on the Form FDA-483, are intended to be an all-inclusive list of your violations. FDA reserves the right to seek any and all other actions and remedies relating to the violations described in this order or any other violations.

⁵ The following discussion of violations does not include FDA's evaluation of Amniotic Therapies' response to the Form FDA-483, which is discussed in a separate section of this order.

⁶ FDA previously inspected Amniotic Therapies in March and April 2015, and documented some of the same violations cited in this order.

Mr. Bryant Gaines
Amniotic Therapies LLC

Receipt

1. Failure to evaluate each incoming HCT/P for the presence and significance of microorganisms, and inspect for damage and contamination. Under the applicable regulations, you must determine whether to accept, reject, or place in quarantine each incoming HCT/P, based upon pre-established criteria designed to prevent communicable disease transmission [21 CFR 1271.265(a)].

For example, you do not perform pre-processing cultures on incoming HCT/Ps, specifically, amnion recovered from cesarean section births, to determine the presence and significance of microorganisms prior to processing HCT/Ps.

2. Failure to establish and maintain procedures, including release criteria, for activities relating to the receipt of HCT/Ps [21 CFR 1271.265(e)].

For example, you have not established and maintained procedures for evaluating incoming HCT/Ps (amnion) for the presence and significance of microorganisms and for determining whether to accept, reject, or place in quarantine incoming HCT/Ps, based upon pre-established criteria designed to prevent communicable disease transmission.

Processing and Process Controls

Failure to process each HCT/P in a way that does not cause contamination or cross-contamination during processing, and that prevents the introduction, transmission, or spread of communicable disease through the use of the HCT/P. You must ensure that specified requirements for in-process controls are met, and that each in-process HCT/P is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received and documented. [21 CFR 1271.220(a) and (c)].

For example, your manufacturing processes do not include in-process controls, such as pre-processing and post-processing/pre-irradiation cultures, to prevent contamination or cross-contamination during processing and to prevent the introduction, transmission, or spread of communicable disease through the use of the HCT/Ps.

Environmental Monitoring

Failure to monitor environmental conditions where they could reasonably be expected to cause contamination or cross-contamination of HCT/Ps or equipment, or accidental exposure of HCT/Ps to communicable disease agents [21 CFR 1271.195(c)].

For example, you do not perform environmental monitoring for the presence of microorganisms in the room where HCT/Ps are processed.

Records

Failure to include in the summary of records a statement that the communicable disease testing was performed by a laboratory that is certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR Part 493 or that has met equivalent requirements determined by the Centers for Medicare and Medicaid Services. The summary of records also failed to contain the name and address of the establishment that made the donor-eligibility determination [21 CFR 1271.55(b)(1) and (3)].

For example, the summary of records that accompanies your HCT/Ps does not contain a statement that the communicable disease testing was performed by a laboratory certified to perform such testing on human specimens under the Clinical Laboratory Act of 1988 or that has met equivalent requirements determined by the Centers for Medicare and Medicaid Services. The summary of records also does not contain the name and address of the establishment that made the donor-eligibility determination.

RESPONSE TO FORM FDA-483

We acknowledge receipt of your written submission dated June 7, 2016, which responds to the inspectional observations on the Form FDA 483 issued at the close of the inspection, and we have reviewed its contents. Your responses fail to demonstrate that you have implemented adequate corrective actions. For example:

1. Process validation. In response to observation 2, you state, among other things, that you have partnered with a third-party facility to design and execute validation protocols of your processing steps. You also mention that AlphaPATCH and AlphaVISION HCT/Ps are terminally sterilized by Sterigenics, which validated the sterilization process using the VD Max Method. However, we cannot evaluate your response because you have provided no documentation to support that you have validated all of the processing steps that you perform on your HCT/Ps.

Although this order does not apply to AlphaGEMS, we also note that a validation study you provided regarding the antibiotic decontamination step that occurs as part of the processing of AlphaGEMS does not sufficiently demonstrate the adequacy of the corrective actions you are taking regarding process validation. For example, the validation study does not include an evaluation of incoming bioburden in order to set adequate acceptance criteria based on the capacity of your process.

We also note that your response states that you will “not be manufacturing amnion product for distribution” while making certain updates to your processing validation. Although we agree in part with this decision, we note that the definition of manufacture in 21 CFR 1271.3(e) includes, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor. It is not clear from your statement that you have ceased all of these steps in the manufacturing process. Moreover, your statement suggests that you would resume “manufacturing . . . for distribution” when

your processing validation updates are complete. However, you have not provided sufficient supporting documentation to allow us to evaluate the adequacy of these updates or your other corrective actions.

2. Receipt. In response to observation 3, you state, among other things, that you are now testing each lot of incoming amnion for the presence of microorganisms, including mycoplasma, and that all testing results will be evaluated before release for distribution. However, we cannot evaluate your response because of a lack of supporting documentation. While your response references a Standard Operating Procedure for the production of AlphaGEMS, you have not provided documentation regarding your other products.

In addition, your response does not discuss the implementation of specific criteria for accepting, rejecting, or placing in quarantine each incoming HCT/P based on an evaluation of the HCT/P for the presence and significance of microorganisms and an inspection of the HCT/P for damage and contamination.

3. Processing and process controls. Your response to observation 4 states, in part, that you have established microbiological testing for incoming amnion, implemented additional in-process controls and testing of final products, and are currently implementing process validation studies. However, due to insufficient supporting documentation, we are unable to evaluate your response.

Under 21 CFR 1271.220(a), you must process each HCT/P in a way that does not cause contamination or cross-contamination during processing, and that prevents the introduction, transmission, or spread of communicable disease through the use of the HCT/P. This requirement is met, in part, through in-process control and testing under 21 CFR 1271.220(c).

Pre-processing cultures are an important in-process control, as discussed in FDA's Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells Tissues and Cellular and Tissue-Based Products (HCT/Ps). If HCT/Ps are processed with a bioburden in excess of the level that a sterilization process has been validated to reduce or eliminate, there is no assurance that processing will reduce or remove bioburden to acceptable limits or reduce the risk of transmission of communicable disease risk. Pre-processing cultures play a critical role in monitoring the process input to ensure that the process capability will not be affected. Thus, terminal sterilization should not be used as an alternative to performing pre-processing cultures. In addition, if you do not perform post-processing/pre-irradiation cultures, or incoming bioburden studies, the type or number of microorganisms on your products is unknown. Therefore, we cannot evaluate to what degree your terminal sterilization process minimizes the risk of communicable disease transmission.

4. Environmental monitoring. In response to observation 6, you state in part that you are working with a third party to develop and implement an environmental monitoring

Mr. Bryant Gaines
Amniotic Therapies LLC

program. However, your response cannot be evaluated due to a lack of supporting documentation. Specifically, you have not provided details regarding what is included in your environmental monitoring program.

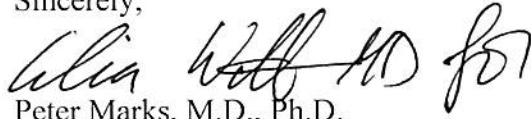
5. Records. Your response to observations 7 and 8 includes, among other things, a statement that you have revised your product inserts to include the required information. However, we cannot evaluate your response because you have not provided supporting documentation.

This letter also confirms the telephone conversation on August 16, 2016, between you and FDA representatives during which FDA notified you that, pursuant to 21 CFR 1271.440(a)(1) and (3), upon receipt of this order, you must cease manufacturing, recall, and destroy HCT/Ps, as set forth above. Please be reminded, as explained during that conversation, that you must not resume operations without prior written authorization from FDA. Before FDA will issue such authorization, you must demonstrate compliance with FDA's regulations in 21 CFR 1271 – including, but not limited to, the Donor Eligibility and current Good Tissue Practice requirements in 21 CFR 1271, Subpart C and Subpart D. Any shipment of HCT/Ps in violation of this order constitutes a violation of Section 368 of the PHS Act [42 USC 271], for which criminal penalties may be imposed.

Within five (5) working days from the receipt of this Order to Cease Manufacturing, Recall, and Destroy, you may request a hearing on the matter in accordance with 21 CFR Part 16 (copy attached), to Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., WO71-G112, Silver Spring, MD 20993-0002 (telephone: 240-402-9153).

Failure to request a hearing within the specified time period constitutes a waiver of the right to a hearing. The Agency's guidelines regarding electronic media coverage of its administrative proceedings can be found at 21 CFR 10, Subpart C.

Sincerely,



Peter Marks, M.D., Ph.D.

Director

Center for Biologics Evaluation and Research

Effective Date: 8/16/16 Time: 3:10 PM

Attachments (2)
21 CFR Part 1271
21 CFR Part 16



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER

CBER-16-03

UPS EXPRESS MAIL & ELECTRONIC MAIL

Mr. Bryant Gaines
Chief Executive Officer
Amniotic Therapies, LLC
11496 Luna Road
Suite 800
Farmers Branch, TX 75234-9417

Dear Mr. Gaines:

During an inspection of your firm, Amniotic Therapies, LLC (Amniotic Therapies), located at 11496 Luna Road, Suite 800, Farmers Branch, TX 75234, conducted between March 23 and May 4, 2016, the United States Food and Drug Administration (FDA) found that your firm receives amniotic tissue that has been recovered from cesarean section births and processes the amnion, a structural tissue, from donors for allogeneic use. During the inspection, FDA further noted that your firm cryo-mills amniotic tissue to manufacture AlphaGEMS Micro and AlphaGEMS Nano products. In addition, FDA noted that your firm manufactures AlphaGEMS product by punching the amniotic tissue to produce 3mm amnion particles.

Based on the labeling, advertising, or other indications of your objective intent available, for example, on your firm's website, AlphaGEMS, AlphaGEMS Micro, and AlphaGEMS Nano are intended for use, among other things, to enhance tissue healing and repair as, for example, adhesion barriers around nerve repairs and for chronic tendinosis, chronic tendinitis, intra-articular injection for chronic inflammatory disease, and intra-articular injection for degenerative joint disease. Accordingly, these products are drugs as defined under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) [21 U.S.C. 321(g)] and biological products as defined in section 351(i) of the Public Health Service Act (PHS Act) [42 U.S.C. 262(i)].

These amniotic-based products (which your firm describes as morselized, micronized, and/or cryomilled) are also human cells, tissues, or cellular or tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d). However, the products are HCT/Ps that do not meet all of the criteria in 21 CFR 1271.10(a) and therefore do not qualify for regulation solely under section 361 of the PHS Act [42 U.S.C. 264] and the regulations in 21 CFR Part 1271. Specifically, the products do not meet the minimal manipulation criterion set forth in section 1271.10(a)(1) and defined for structural tissue in section 1271.3(f)(1), because the cryo-milling and punching

processes alter the original relevant characteristics of the structural tissue relating to the tissue's utility for reconstruction, repair, or replacement. In addition, these amniotic-based products do not meet the homologous use criterion set forth in 21 CFR 1271.10(a)(2) and defined in section 1271.3(c), because the labeling, advertising, or other indications of your objective intent available, for example, on your firm's website, indicate that these products are intended for use as an adhesion barrier and have numerous common applications related to "healing" and "repair," such as those noted above, which are not homologous uses of amniotic membrane. Homologous uses of amniotic membrane include covering, protecting, serving as a selective barrier for the movement of nutrients between the external and in utero environment, and retaining fluid in utero.

Please be advised that in order to lawfully market a drug that is also a biological product, a valid biologics license must be in effect [42 U.S.C. 262(a)]. Such licenses are issued only after a showing of safety and efficacy for the product's intended use. While in the development stage, such products may be distributed for clinical use in humans only if the sponsor has an investigational new drug (IND) application in effect as specified by FDA regulations [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312]. The AlphaGEMS, AlphaGEMS Micro, and AlphaGEMS Nano products are not the subject of an approved biologics license application (BLA), nor are there INDs in effect for any of these products.

Additionally, during the inspection, FDA investigators documented evidence of significant deviations from current good manufacturing practice (CGMP) in the manufacture of AlphaGEMS, AlphaGEMS Micro, and AlphaGEMS Nano products. These deviations from CGMP include deviations from the applicable requirements of Section 501(a)(2)(B) of the FD&C Act, Sections 351(a) of the PHS Act, and 21 CFR Parts 210 and 211.

At the close of the inspection, FDA issued a Form FDA 483, Inspectional Observations, which FDA subsequently revised and issued to you in amended form on May 24, 2016. The inspection revealed a number of significant objectionable conditions relating to your firm's compliance with CGMP. These include, but are not limited to, the following:

1. Failure to establish and follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile [21 CFR 211.113(b)]. For example:

- a. Approximately 25 of 249 vials of AlphaGEMS manufactured from amnion recovered from a single donor (lot# 150792) on April 29, 2015, were distributed and linked to four adverse events, including two infections from *Mycoplasma hominis*. Two unopened vials from the same lot were tested by an outside laboratory and confirmed positive for *M. hominis*. Even if AlphaGEMS is no longer labeled as sterile, the product purports to be sterile and is expected to be sterile by the nature of its intended use and method of administration. For example, your firm's website states that the product is "easy to inject" and "may be applied directly to interior or exterior wounds" or "damaged tissue." Furthermore, your firm's website states that AlphaGEMS undergoes sterility testing.

- b. Environmental monitoring for the presence of microorganisms is not conducted during the manufacture of AlphaGEMS, AlphaGEMS Micro, and AlphaGEMS Nano. As with AlphaGEMS, AlphaGEMS Micro and AlphaGEMS Nano purport to be sterile by the nature of their intended uses and method of administration. Furthermore, the Amniotic Therapies website states that these products undergo sterility testing.
- 2. **Failure to establish and follow written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess [21 CFR 211.100(a) and (b)]. For example:**
 - a. The manufacturing process has not been adequately validated for AlphaGEMS, AlphaGEMS Micro, and AlphaGEMS Nano.
 - b. Changes to the production processes for AlphaGEMS, AlphaGEMS Micro, and AlphaGEMS Nano have not been validated. Specifically, mycoplasma testing was conducted on seven lots of AlphaGEMS and one lot of AlphaGEMS Nano which remained in inventory in response to reports of four adverse events for AlphaGEMS product. The additional testing was a change to the established production process and was not validated. Approximately 200 vials from five of the AlphaGEMS lots were subsequently distributed.
- 3. **Failure to establish and follow written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures [21 CFR 211.80(a)].** Specifically, there are no written procedures describing in sufficient detail the criteria for approval or rejection of amnion, based on the results of pre-processing cultures and supported by validation of the manufacturing process.
- 4. **Failure to maintain laboratory controls that include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include a determination of conformance to written descriptions of sampling procedures and appropriate specifications for drug products [21 CFR 211.160(b)].**
- 5. **Failure to test the AlphaGEMS, AlphaGEMS Micro, and AlphaGEMS Nano products, non-penicillin drug products, for the presence of penicillin although a reasonable possibility exists that the non-penicillin drug products have been exposed to cross contamination with penicillin [21 CFR 211.176].** Specifically, penicillin was used in an antibiotic wash during manufacture of approximately 1,100 vials of AlphaGEMS Micro and approximately 400 vials of AlphaGEMS from November 2015 to February 2016 and there is no documentation that testing for penicillin has been performed.

Additionally, FDA observed significant deviations in the manufacture of your amnion intermediates during the inspection. Specific areas of concern include, but are not limited to:

PRODUCTION AND PROCESS CONTROLS

6. Your firm has not adequately validated the manufacturing process for your amnion intermediates for AlphaGEMS, AlphaGEMS Micro, and AlphaGEMS Nano.
7. An antibiotic cocktail wash was added to the production procedure for the manufacturing of your amnion intermediates for AlphaGEMS, AlphaGEMS Micro, and AlphaGEMS Nano in November 2015, in response to the reports of adverse reactions in September 2015. This process change was not validated.
8. Environmental monitoring for the presence of microorganisms is not conducted during the manufacture of the amnion intermediates for AlphaGEMS, AlphaGEMS Micro, and AlphaGEMS Nano.
9. There are not adequate written procedures that describe the in-process controls, and tests, or examinations to be conducted on the amnion intermediates for AlphaGEMS, AlphaGEMS Micro, and AlphaGEMS Nano, to assure batch uniformity and integrity.

CONTROL OF COMPONENTS

10. There are not adequate procedures for receipt, identification, storage, handling, sampling, testing, and approval or rejection of the following supplies and components used to wash and incubate the amnion intermediates.
 - a. The PBS and 50 mL conical sterile tubes used to wash the amnion tissue.
 - b. T-175 flask and RPMI 1640 used to incubate the cut amnion.
 - c. The Antibiotic – Antimycotic used to prevent bacterial and fungal growth on the amnion tissue.

REVIEW OF YOUR INSPECTIONAL RESPONSES

We acknowledge receipt of your written response dated June 7, 2016, which responds to the inspectional observations on the Form FDA 483, and we have reviewed its contents. We have concluded that the response does not provide sufficient detail to fully assess the adequacy of your corrective actions. In addition, we have the following specific comments.

Form FDA 483 Observation 2

Your firm's process validation does not include an evaluation of incoming bioburden in order to set adequate acceptance criteria based on the capacity of your process. In addition, we note that a 3-log reduction does not provide much assurance from the introduction, transmission or spread of communicable disease, unless the incoming amnion has extremely low bioburden.

Form FDA 483 Observation 3

Your response noted that each lot of incoming amnion is tested for microorganisms, including mycoplasma, and that the results are evaluated prior to distribution. However, the response does not specify rejection criteria for high bioburden and/or objectionable microorganism(s). Nor does your response describe Amniotic Therapies' plan to mitigate the potential for cross contamination when amnion with high bioburden and/or objectionable microorganisms is processed in the same facility with the same equipment.

Neither this letter, nor the observations listed on the Form FDA 483, is intended to be an all-inclusive list of your firm's deviations from applicable laws and regulations. It is your responsibility to ensure that your firm is in compliance with the provisions of the FD&C Act, PHS Act, and all applicable Federal laws and regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

For further information about IND requirements, contact Dr. Patrick Riggins, Director of Regulatory Management Staff, Office of Cellular, Tissue, and Gene Therapies, at (240) 402-8346. Please include a copy of this letter with your initial submission to CBER.

Please notify this office in writing, within 15 working days of receipt of this letter, of any additional steps you have taken or will take to correct the noted deviations and to prevent their recurrence. Include any documentation necessary to show that corrective action has been achieved. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to me at the following address: U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., WO71 - G112, Silver Spring, MD 20993-0002. If you have any questions regarding this letter, please contact the Division of Case Management, CBER at 240-402-9155.

Sincerely,



Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

From: Kaplan, Scott [<mailto:Scott.Kaplan@fda.hhs.gov>]
Sent: Tuesday, June 21, 2016 12:12 PM
To: Douglas B. Farquhar
Cc: Unlu, Mustafa
Subject: RE: AT 483

Doug,

I understand from the firm's recent submission that they were not aware of the FOIA information for CDC. I believe the correct contact person is Katherine S. Norris and the website for submitting FOIA requests to CDC is: <http://www.cdc.gov/od/foia/request/index.htm>.

Best,
Scott

From: Kaplan, Scott
Sent: Thursday, May 19, 2016 6:32 PM
To: 'Douglas B. Farquhar'
Cc: Unlu, Mustafa (Mustafa.Unlu@fda.hhs.gov)
Subject: RE: AT 483

Doug,

I have confirmed that those records must be obtained from CDC. I am trying to pin down a contact in CDC's OGC for you to speak with and hope to have that tomorrow. As for the MedWatch reports, I am unable to obtain copies at this time and have been advised by CBER that they can only be released through our FOI process. Please note that going forward my colleague Mustafa Unlu, copied, will be handling this matter.

Thank you,
Scott

Scott Kaplan
Associate Chief Counsel
U.S. Food and Drug Administration
10903 New Hampshire Ave. WO-32-4324
Silver Spring, MD 20993
301.796.8576
scott.kaplan@fda.hhs.gov

From: Douglas B. Farquhar [<mailto:DFarquhar@hpm.com>]
Sent: Wednesday, May 18, 2016 12:06 AM
To: Kaplan, Scott
Subject: RE: AT 483

We do have the test results, but, of course, the testing data, the chain of custody/shipping data, and any documentation of the underlying examination are all pending requests. Thank you, Scott.

From: Kaplan, Scott [<mailto:Scott.Kaplan@fda.hhs.gov>]
Sent: Tuesday, May 17, 2016 4:26 PM
To: Douglas B. Farquhar
Subject: AT 483

Doug,

I am still working with CBER on the questions you posed this afternoon, but with respect to Observation 1 of the Form FDA 483, I did receive confirmation from CBER the investigator mistakenly stated that four units of HCT/Ps had been tested by an outside laboratory. I am informed that only two units were tested – I believe you stated that the firm has the results of those analyses, is that correct?

Best and safe travels,
Scott

Scott Kaplan
Associate Chief Counsel
U.S. Food and Drug Administration
10903 New Hampshire Ave. WO-32-4324
Silver Spring, MD 20993
301.796.8576
scott.kaplan@fda.hhs.gov

This e-mail is sent by a law firm and may contain information that is
privileged or confidential. If you are not the intended recipient, please
delete the e-mail and any attachments and notify us immediately.

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

DOUGLAS B. FARQUHAR

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D.C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329
www.hpm.com

Direct Dial (202) 737-9624
DFarquhar@hpm.com

July 11, 2016

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

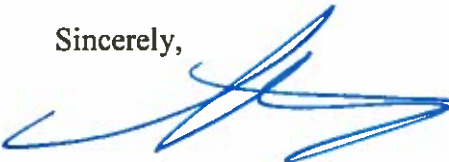
Dear Sir or Madam,

Pursuant to the Freedom of Information Act ("FOIA") at 5 U.S.C. § 552, we hereby request the following:

Copies of all adverse reaction reports received by FDA in 2015 or 2016, involving amniotic tissue products manufactured by Amniotic Therapies LLC

We will pay all reasonable fees in supplying this information. If these fees should exceed \$250, please contact me for authorization to proceed. If you have any questions regarding this request, please do not hesitate to contact me. We ask that you please adhere to the statutory and regulatory requirements governing access to public information (5 U.S.C. § 552; 45 C.F.R. Part 5) and provide the requested documents within the statutory deadline of 20 days.

Sincerely,

for: 
Douglas B. Farquhar



FOIA Request Confirmation

Confirmation Number: FDA1627256

Requester:

General

Description of Requester:	Commercial user
Max Amount Willing to Pay:	\$250

Organization

Organization Name: Hyman, Phelps & McNamara			
Primary Phone:	202-737-9624	Other Phone:	
Email:		SGoldman@hpm.com	

Mailing Address

Address 1:	700 13th St. NW
Address 2:	
City:	Washington
State:	DC
Zip Code:	20005

Billing Address

Address 1:	700 13th St. NW
Address 2:	
City:	Washington
State:	DC
Zip Code:	20005

Details

Requester Name:	Douglas B. Farquhar		
Requester File #:		Request Letter:	Scan from XR Mailroom.pdf
Requested Date From:		Requested Date To:	
Subject of Request:	Copies of all adverse reaction reports received by FDA in 2015 or 2016, involving amniotic tissue products manufactured by Amniotic Therapies		

Waiver of Fees

Justification:	
----------------	--

Expedited Processing

Reason:	
Justification:	

[Print](#) [Create Another Request](#) [Close](#)

Within one business day of the submission of your online request, you will receive by electronic mail an FOIA Control Number. If you need to communicate with FDA regarding your request, please refer to this Control Number. Requests received after 4:00 P.M. E.S.T. will be considered to have been received on the following business day.

If your informational needs change, and you need to cancel your request, please contact the Division of Freedom of Information by telephone, mail, or fax. Please include your control number in the correspondence. For contact information, please see [FDA's FOIA page](#).

LAW OFFICES
HYMAN, PHELPS & McNAMARA, P.C.

DOUGLAS B. FARQUHAR

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, D.C. 20005-5929
(202) 737-5600
FACSIMILE
(202) 737-9329

www.hpm.com

Direct Dial (202) 737-9624
DFarquhar@hpm.com

July 11, 2016

Katherine S. Norris
Chief FOIA Officer
Centers for Disease Control and Prevention
OD/OCOO/OCIO
1600 Clifton Road
Atlanta, GA 30329

Subject: FOIA request on behalf of Amniotic Therapies LLC

Dear Ms. Norris,

Scott Kaplan, in FDA's Office of Chief Counsel, requested that we direct our Freedom of Information Act request to the Centers for Disease Control and Prevention (CDC) through you.

We are writing in reference to two vials of AlphaGems amniotic tissue (lot # 150792), manufactured by Amniotic Therapies LLC (Amniotic Therapies), that were sent from St. Vincent Charity Medical Center, in Cleveland Ohio, to the University of Alabama Diagnostic Mycoplasma Laboratory, and were found by that lab to be positive for ureaplasma or mycoplasma on January 7, 2016 and January 26, 2016. These test results were discussed in the Food and Drug Administration's Form 483 issued to Amniotic Therapies on May 24, 2016, which stated that: "...two vials of the lot were tested positive [sic] for *Mycoplasma hominis* by an outside laboratory."

As a result, pursuant to the Freedom of Information Act (FOIA) at 5 U.S.C. § 552, we hereby request the following:

- **Copies of all documents showing any part of the chain of custody of the two above-referenced vials of AlphaGems amniotic tissue (lot # 150792) manufactured by Amniotic Therapies, from the time that they left St. Vincent Charity Medical Center, through their arrival at the University of Alabama Diagnostic Mycoplasma Laboratory, and including all documents showing any part of the chain of custody of the two vials while they were at the University of Alabama prior to, and during, the testing process;**

July 11, 2016

Page 2

- **Copies of all documents reflecting the type of packaging that the two AlphaGems vials were contained in when they arrived at the University of Alabama and, if the two vials were first sent to CDC, then copies of all documents reflecting the type of packaging that the two vials were contained in when they arrived at CDC, including documents reflecting any inspection of the packaging and the vials for damage and breaches to their integrity;**
- **Copies of all documents reflecting the temperature that the two vials were kept at throughout their journey from St. Vincent Charity Medical Center, including if they were first sent to CDC, through their arrival at the University of Alabama;**
- **Copies of all documents reflecting the storage conditions of the two vials while the vials were kept at CDC prior to shipping to the University of Alabama;**
- **Copies of all documents reflecting the person or people who were in charge of the laboratory that performed the testing on the two vials at the University of Alabama, including the names of all of the individuals who performed the tests on the two vials, their qualifications for performing such tests, and whether the laboratory in question is CLIA certified;**
- **Copies of all documents showing the testing results of the amniotic tissue in the two AlphaGems vials;**
- **Copies of all reports, memos and other documents that describe, explain or in any way interpret the testing results of the amniotic tissue in the two AlphaGems vials;**
- **Copies of all documents showing the methodology used for testing samples, such as the samples of amniotic tissue in the two AlphaGems vials, and the sensitivity and specificity of this methodology in detecting the reported contamination;**
- **Copies of all documents showing the qualification and calibration history of all instruments and equipment that were used in testing the amniotic tissue in the two AlphaGems vials.**


We will pay all reasonable fees in supplying this information. If these fees should exceed \$250, please contact me for authorization to proceed. If you have any questions regarding this request, please do not hesitate to contact me. We ask that you please adhere to the statutory and regulatory requirements governing access to public information (5 U.S.C. § 552; 45 C.F.R. Part 5) and provide the requested documents within the statutory deadline of 20 days.

HYMAN, PHELPS & MCNAMARA, P.C.

July 11, 2016

Page 3

Sincerely,

For: 
Douglas B. Farquhar



Submit a FOIA Request

Your Freedom of Information Act (FOIA) request has been received. Within two weeks, you should receive a postcard confirming receipt of your request. The postcard will provide you with a FOIA request tracking number to be used as a FOIA request/logging number by this FOIA Requester Service Center.

Related Links

- [What Happens To My FOIA Request?](#)

Page last reviewed: May 25, 2016

Page last updated: May 25, 2016

Content source: Centers for Disease Control and Prevention (/index.htm) , Freedom of Information Act (FOIA) /od/foia/index.htm)



Food and Drug Administration
Silver Spring MD 20993

August 10, 2016

Douglas Farquhar
Hyman, Phelps & McNamara, P.C.
700 13th St, NW Suite 1200
Washington, DC 20005

In reply refer to file: F16-5754

Dear Mr. Farquhar,

This is in reply to your Freedom of Information Act request dated July 11, 2016, in which you requested "copies of all adverse reaction reports received by FDA in 2015 and 2016, involving amniotic tissue products manufactured by Amniotic Therapies, LLC." Your request was received in the Center for Biologics Evaluation and Research on July 13, 2016.

A query of our database located the enclosed responsive records.

We have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response, to:

Ms. Catherine Teti
Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Please clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact:

Beth Brockner-Ryan, Branch Chief
Center for Biologics Evaluation and Research (CBER)
Access Litigation and Freedom of Information Branch
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building 71, Room 1114
Silver Spring, MD 20993-0002
Email: beth.brocknerryan@fda.hhs.gov
Main Line 240-402-7800
FOI Line 240-402-8008

You may also contact the HHS FOIA Public Liaison for assistance at:

Michael Bell
HHS FOIA Public Liaison
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
Telephone: (202) 260-0793
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road—OGIS
College Park, MD 20740-6001

Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov
Fax: 202-741-5769

The following may be included in a monthly invoice:

Search	1/4 Hour @ \$46.00/hr	\$11.50
Review	1 Hour @ \$46.00/hr	\$57.50
TOTAL		\$57.50



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

The above charges may not reflect final charges for this request. Please DO NOT send any payment until you receive an invoice from the Agency's Freedom of Information Staff (HFI-35).

If you have any questions or if we can be of further assistance, please let us know by referencing the above file number. You can contact Catherine Wilusz by phone at 240-402-8008 or by e-mail at Catherine.wilusz@fda.hhs.gov.

Sincerely,

Beth Brockner Ryan

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch

U.S. Department of Health and Human Services

Individual Health Professional Report

Form Approved: OMB No. 0910-0291, Expires 12/31/2011
See OMC statement on revision.**MEDWATCH**The FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors**FOR USE ONLY**Time and
sequence #

0-20-31

A. PATIENT INFORMATION

1. Patient Identifier (b)(6)	2. Age at Time of Event or Date of Birth. 7/6/2015 (b)(6)	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight lb or 90.1 kg
---------------------------------	--	---	-------------------------------

In confidence

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply.

1. ☒ Adverse Event ☐ Product Problem (e.g. defects/malfunctions)
☒ Product Use Error ☐ Problem with Different Manufacturer of Same Medication

2. Outcomes Attributed to Adverse Event
(Check all that apply)

☐ Death (mm/dd/yyyy) ☐ Disability or Permanent Impairment
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☒ Hospitalization - initial or prolonged ☐ Other Serious (Important) Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy) 09/21/2015

4. Date of this Report (mm/dd/yyyy) 10/20/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data including Dates

See additional page(s) for complete text.

7. Other Relevant History, including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)**C. PRODUCT AVAILABILITY**

Product Available for Evaluation? (Does not same product to FDA)

☒ Yes ☐ No ☐ Returned to Manufacturer on (mm/dd/yyyy)**D. SUSPECT PRODUCT(S)**

1. Name, Strength, Manufacturer (from product label)

#1 Name: Aspirin

Strength: 81 mg

Manufacturer: Bristol-Myers

#2 Name:

Strength:

Manufacturer:

FORM FDA 3500 (1/09)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

2. Dose or Amount		Frequency	Route
#1			
#2			
3. Dates of Use (if unknown, give duration) from/to (or best estimate)			3. Event Abated After Use Stopped or Dose Reduced?
#1			#1 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2			#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
4. Diagnosis or Reason for Use (Indication)			8. Event Reappeared After Reintroduction?
#1			#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2			#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
6. Lot #	7. Expiration Date	9. NDC # or Unique ID	
#1 (b)(6)	#1		
#2	#2		

E. SUSPECT MEDICAL DEVICE

1. Brand Name

Manufacturer Name

Manufacturer Name, City and State

del #

Lot #

Operator of Device

Health Professional

atalog #

Expiration Date (mm/dd/yyyy)

Lay User/Patient

serial #

Other #

Other

C. If Implanted, Give Date (mm/dd/yyyy) / If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER CONCOMITANT MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment or event)

G. REPORTER (See confidentiality section on back)

1. Name and Address

Name (b)(6)

Address

City

State

ZIP

2. Health Professional's Occupation

(b)(6)

4. Also Reported to:

☒ Manufacturer

☐ User Facility

☒ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

AEP 3295

080331

B.5. Describe Event or Problem (continued)

Patient had spinal fusion surgery on 8/19/15. Alphacem product was mixed with other product and placed into the posterior lumbar 13-4. Patient returned on 8/21/15 with complaint of pain from incision. CT showed superficial fluid collection. Return to surgery for debridement. Cultures collected from deep wound grew *Propionibacterium acnes* and *Staphylococcus aureus*. Packaging of Alphacem was labelled aseptic. Initial package instructions also stated that it could be used on the sterile field. A later version was given to us, saying that the product should not be used on the sterile field and only the contents in the vial were considered aseptic.

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

8/21/15 CT showed superficial fluid collection. 9/21/15 culture from deep back wound grew *Staphylococcus aureus*. 8/21/15 debridement wound grew variable bacilli and *Pseudomonas aeruginosa*. Cultures collected on 8/23, 8/26, 9/20 also grew positive Gram variable bacilli associated by culture laboratory at myelogram, drainage.

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., diabetes, heart, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

RUN DATE: 05/24/16

RUN TIME: 1341

RUN USER: (b)(6)

(b)(6)

LAB *LIVE*

PAGE 1

*** PATIENT CARE INQUIRY - LAB ***

PCI User: (b)(6)

Lab Database: LAB (b)(6)

(b)(6)		Sex: M At		
(b)(6)		Status: D16 IN	Location: G 6A	G 614-01
Specimen: (b)(6)	Collected: 09/21/15-1036	Status: COMP	Req#: 03561740	
	Received: 09/21/15-1212	Source: BACK, LOWER	Sp Desc: SWAB	RES
Ordered: WOUND CULTURE				
Comments: CONSERVATION				
Procedure	Result	Verified	Site	
WOUND CULTURE Final		09/23/15-1209		
Organism 1	STAPHYLOCOCCUS HAEMOLYTICUS			
QUANTITATION:	LIGHT GROWTH			
ISOLATE COMMENT:	METHICILLIN RESISTANT			
1. STAPHYLOCOCCUS HAEMOLYTICUS				
	ROUTE DOSE	INTERP	M.I.C.	COST
AMP/SULBACTAM		R	<=8/4	
DAPTOMYCIN		S	<=0.5	
AMOX/K CLAV'ATE		R	<=4/2	
CEFTRIAXONE		R	32	
CIPROFLOXACIN		R	>2	
CLINDAMYCIN		R	>4	
ERYTHROMYCIN		R	>4	
GENTAMICIN	IM/IV 1.0-1.7 MG/KG Q8H	I	8	5.00
OXACILLIN		R	>2	
RIFAMPIN	PO 300 MG PO Q12H	S	<=1	
SYNERCID		S	<=0.5	
TETRACYCLINE		R	>8	
TRIMETH/SULFA		R	>2/38	
VANCOMYCIN		S	1	
LEVOFLOXACIN		R	>4	
LINEZOLID	IV 600 MG IVPB Q12H	S	<=1	30.00
	PO 600 MG PO Q12H	S		6.00

RUN DATE: 05/24/16

RUN TIME: 1341

RUN USER: (b)(6)

(b)(6)

LAB *LIVE*

PAGE 2

*** PATIENT CARE INQUIRY - LAB ***

PCI User: (b)(6)

Lab Database: LAB (b)(6)

(b)(6)

Sex: M Attend Dr:

Status: DIS IN

Location: G 6A

G.614-01

Specimen: (b)(6)

Collected: 09/21/15-1036 Status: COMP Req#: 03561740
Received: 09/21/15-1212 Source: BACK, LOWER Sp Desc: SWAB

Ordered: WOUND CULTURE

Comments: CONSERVATION

Procedure	Result	Verified	Site
-----------	--------	----------	------

WOUND CULTURE Final (continued)

S = Susceptible I = Intermediate

NS = Nonsusceptible

R = Resistant

R* = Predicted resistant interpretation

EBL? = Suspected ESBL

ESBL = Confirmed Extended Spectrum Beta-Lactamase

N/R = NOT REPORTED

BLAC = BETA LACTAMASE POSITIVE

COST = COST CODE

TFG = THYMIDINE DEPENDENT STRAIN

MIC = MCG/ML (MG/L)

BLANK = DATA NOT AVAILABLE, OR

DRUG NOT ADVISABLE/TESTED

- A) USE MAXIMUM DOSES OF DRUGS WITH AN AMINOGLYCOSIDE FOR P. AERUGINOSA IN PATIENTS WITH GRANULOCYTOPENIA OR SERIOUS INFECTIONS.
- B) BREAKPOINTS BASED ON PARENTERAL DOSE. FOR CEFUROXIME PO USE <8=S, 8-16=I, >16=R
- C) FOR STREPTOCOCCI AND NON-BETA LACTAMASE PRODUCING ENTEROCOCCI REFER TO PENICILLIN INTERPRETATION
- D) NITROFURANTOIN IS CONTRAINDICATED IN PATIENTS WITH CrCl<60 mL/min.
- E) IF KPC CONFIRMED, THIS ISOLATE DEMONSTRATES CARBAPENEMASE PRODUCTION. THE CLINICAL EFFICACY OF THE CARBAPENEMS HAS NOT BEEN ESTABLISHED FOR TREATING INFECTIONS CAUSED BY Enterobacteriaceae THAT TEST CARBAPENEM SUSCEPTIBILITY (eg. MIC ertapenem < OR = 2 ug/mL, imipenem < or = 4 ug/mL, AND/OR meropenem < or = 4 ug/mL) BUT DEMONSTRATE CARBAPENEMASE PRODUCTION in vitro.

---INTERPRETATIONS BASED ON APPROXIMATE ADULT ATTAINABLE SYSTEMIC/URINE LEVELS. DOSAGES ARE ONLY GUIDELINES; CONSIDER WEIGHT, ACUTY, AND RENAL/HEPATIC FUNCTION

WHEN DETERMINING THERAPEUTIC DOSE. URINE INTERPRETATIONS ARE FOR LOWER UTI ONLY.

RUN DATE: 05/24/16
 RUN TIME: 1341
 RUN USER: (b)(6)

(b)(6) LAB *LIVE*
 *** PATIENT CARE INQUIRY - LAB ***
 PCI User: (b)(6) Lab Database: LAB (b)(6)

PAGE 3

(b)(6)		lex:M Attend Dr: F	
(b)(6)		Status: DIS IN	Location: G.6A G.614-01
Specimen: (b)(6)	Collected: 09/21/15-1036	Status: COMP	Req#: 03561740
	Received: 09/21/15-1212	Source: BACK, LOWER	Sp Desc: SWAB
Ordered: WOUND CULTURE Comments: CONSERVATION			
Procedure	Result	Verified	Site
WOUND CULTURE Final (continued)			
INTERPRETATIONS BASED ON NCCLS M100-S12 JANUARY 2011			

RUN DATE: 05/24/16
 RUN TIME: 1341
 RUN USER: (b)(6)

(b)(6) LAB *LIVE*
 *** PATIENT CARE INQUIRY - LAB ***
 PCI User: (b)(6) Lab Database: LAB (b)(6)

PAGE 1

(b)(6)		Sex: M Attend Dr:	
Status: DIS IN		Location: G.6A G 614-01	

Specimen: (b)(6)	Collected: 09/21/15-1440	Status: COMP	Req#: 03561931
	Received: 09/21/15-1503	Source: LUMBAR	Sp Desc: OTHER

Ordered: ANAER CULTURE, AEROBIC CULT
 Comments: CONSERVATION
 SWAB PRELAVAGE LUMBAR WOUND.

Procedure	Result	Verified	Site																												
ANAEROBIC CULTURE	Final	10/08/15-0757																													
<p>Organism 1 <u>PROPIONIBACTERIUM ACNES</u></p> <p>QUANTITATION: FEW COLONIES</p> <p>BETA LACTAMASE: NEGATIVE</p> <p>ISOLATE COMMENT: SENSITIVITIES PERFORMED AT QUEST</p>																															
<p><u>1. PROPIONIBACTERIUM ACNES</u></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;">ROUTE DOSE</th> <th style="width: 10%;">INTERP</th> <th style="width: 10%;">M.I.C.</th> <th style="width: 40%;">COST</th> </tr> </thead> <tbody> <tr> <td>CEFOXITIN</td> <td>S</td> <td><=16</td> <td></td> </tr> <tr> <td>CLINDAMYCIN</td> <td>S</td> <td><=2</td> <td></td> </tr> <tr> <td>IMIPENEM</td> <td>S</td> <td><=4</td> <td></td> </tr> <tr> <td>PENICILLIN</td> <td>S</td> <td><=0.5</td> <td></td> </tr> <tr> <td>PIP/TAZ</td> <td>S</td> <td><=32</td> <td></td> </tr> <tr> <td>METRONIDAZOLE</td> <td>R</td> <td>>32.0</td> <td></td> </tr> </tbody> </table>				ROUTE DOSE	INTERP	M.I.C.	COST	CEFOXITIN	S	<=16		CLINDAMYCIN	S	<=2		IMIPENEM	S	<=4		PENICILLIN	S	<=0.5		PIP/TAZ	S	<=32		METRONIDAZOLE	R	>32.0	
ROUTE DOSE	INTERP	M.I.C.	COST																												
CEFOXITIN	S	<=16																													
CLINDAMYCIN	S	<=2																													
IMIPENEM	S	<=4																													
PENICILLIN	S	<=0.5																													
PIP/TAZ	S	<=32																													
METRONIDAZOLE	R	>32.0																													
<p>@PLEASE ADD APPROPRIATE CHARGES FOR WHAT WAS PERFORMED AT @REF LAB</p>																															
<p><u>AEROBIC CULTURE</u> <u>Final</u> 10/14/15-1141</p> <p>Organism 1 <u>GRAM VARIABLE RODS</u></p> <p>QUANTITATION: MODERATE GROWTH</p> <p>ISOLATE COMMENT: SENT TO CCF FOR ID. 9/30</p> <p>ISOLATE COMMENT 2: ORGANISM NON-VIABLE</p>																															

RUN DATE: 05/24/16

RUN TIME: 1341

RUN USER: (b)(6)

(b)(6)

LAB *LIVE*

PAGE 1

*** PATIENT CARE INQUIRY - LAB ***

PCI User: (b)(6)

Lab Database: LAB. (b)(6)

(b)(6)		lex:M Attend Dr:	
Status: DIS IN		Location: G.6A	G 614-01
Specimen: (b)(6)	Collected: 09/23/15-1043	Status: COMP	Req#: 03563389
	Received: 09/23/15-1319	Source: LUMBAR	Sp Desc: OTHER
Ordered: ANAER CULTURE, AEROBIC CULT Comments: CONSERVATION PRE-LAVAGE SWAB			
Procedure	Result	Verified	Site
ANAEROBIC CULTURE Final NO ANAEROBES ISOLATED 10 DAYS		10/04/15-1123	
AEROBIC CULTURE Final Organism 1 QUANTITATION: ISOLATE COMMENT: ISOLATE COMMENT 2:	GRAM VARIABLE RODS LIGHT GROWTH SENT TO CCF FOR ID. 9/30 ORGANISM NON-VIABLE	10/14/15-1142	

RUN DATE: 05/24/16

(b)(6)

LAB *LIVE*

PAGE 1

RUN TIME: 1342

*** PATIENT CARE INQUIRY - LAB ***

RUN USER: (b)(6)

PCI User: (b)(6) Lab Database: LAB (b)(6)

: (b)(6)		Sex: M Attend Dr: -	
Status: DIS IN		Location: G.6A	G.614-01
Specimen: (b)(6)	Collected: 09/23/15-1043	Status: COMP	Req#: 03563396
	Received: 09/23/15-1322	Source: BACK	Sp Desc: OTHER
	Subm Dr:		
Ordered: ANAER CULTURE, AEROBIC CULT			
Comments: CONSERVATION			
BACK WOUND CULTURE (TISSUE)			
Procedure	Result	Verified	Site
ANAEROBIC CULTURE Final		10/04/15-1123	
NO ANAEROBES ISOLATED 10 DAYS			
AEROBIC CULTURE Final		10/14/15-1142	
Organism 1	GRAM VARIABLE RODS		
QUANTITATION:	LIGHT GROWTH		
ISOLATE COMMENT:	SENT TO CCF FOR ID. 9/30		
ISOLATE COMMENT 2:	ORGANISM NON-VIABLE		

U.S. Department of Health and Human Services

Internet Health Professional Report

Form Approved OMB No. 0910-0291, Expires 12/31/16
See OMB statement at: www.gpo.gov/omb**MEDWATCH**The FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors

FDA USE ONLY

Image unit
sequence #

00000000000000000000

A. PATIENT INFORMATION

1. Patient Identifier (b)(6)	2. Age at Time of Event or Date of Birth: (b)(6)	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight lb or 111 kg
---------------------------------	--	---	---------------------------

In confidence

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply.

1. ☒ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☒ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine
2. Outcomes Attributed to Adverse Event
(Check all that apply)
- ☐ Death (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☒ Hospitalization, initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)

(9/16/2015)

4. Date of this Report (mm/dd/yyyy)

10/01/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, including Dates

See additional page(s) for complete text.

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

☒ Yes ☐ No ☐ Returned to Manufacturer on (mm/dd/yyyy)**D. SUSPECT PRODUCT(S)**

1. Name, Strength, Manufacturer (from product label)

#1 Name: 1 mg/0.5 mg

Strength: 0.0 mg

Manufacturer: 1 mg/0.5 mg

#2 Name:

Strength:

Manufacturer:

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use (if unknown, give duration) from/to (or best estimate)

#1

#2

4. Diagnosis or Reason for Use (Indication)

#1

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☒ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☒ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

7. Expiration Date

#1

#2

8. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

Lot #

Catalog #

Expiration Date (mm/dd/yyyy)

Lot #

Other #

Implanted, Give Date (mm/dd/yyyy)

If Explanted, Give Date (mm/dd/yyyy)

Is a Single-Use Device that was Reprocessed and Reused on a Patient?

Yes ☐ No ☒

If Yes, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

List names and therapy dates (include treatment of event)

G. REPORTER (See confidentiality section on back)

Name (b)(6)	Address (b)(6)
City (b)(6)	State (b)(6) ZIP (b)(6)
Phone # (b)(6)	E-mail (b)(6)

2. Health Professional? ☐ 3. Occupation (b)(6)

4. Also Reported to ☒ Manufacturer ☐ User Facility ☒ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

FORM FDA 3600 (1/09)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

PLEASE TYPE OR USE BLACK INK

AEP 3294

22

B.5. Describe Event or Problem (continued)

patient had neck fusion surgery on 9/3/15. Returned to surgery on 9/16/15 for T12-L1 laminectomy. Serbarnick's drainage tray post op and unexplained temperature elevation noted and indicated. Lumbar fluid and swab collected for culture. Packaging was labeled as sterile and placed on sterile field. Days later, company told us that only the contents of vial were sterile and changed the product IFU sheet.

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

9/15/15 C1 showed superficial fluid collection at T12-C2 9/14/15 WBC count 14.4 9/14/15 culture: gram stain.

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, etc., pregnancy status and chronic conditions, diabetes, hypertension, etc.) (continued)

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

RUN DATE: 05/24/16

RUN TIME: 1343

RUN USER: (b)(6)

(b)(6) LAB *LIVE*

PAGE 1

*** PATIENT CARE INQUIRY - LAB ***

PCI User: (b)(6) Lab Database: LAB (b)(6)

Name:

(b)(6)

Sex: M Attend Dr

Status: DIS IN

Location: G.5E

G.549-01

Specimen: (b)(6)

Collected: 09/18/15-0848 Status: COMP

Req#: 03560139

Received: 09/18/15-1207 Source: LHMREP

On Desc: FLUID

Subm Dr:

Ordered: WOUND CULTURE

Comments: CONSERVATION

Procedure

Result

Verified

Site

WOUND CULTURE Final

Organism 1

STAPH EPIDERMIDIS, METH RESIST

09/20/15-0726

QUANTITATION:

LIGHT GROWTH

1. STAPH EPIDERMIDIS, METH RESIST

	ROUTE	DOSE	INTERP	M.I.C.	COST
AMP/SULBACTAM			R	<=8/4	
DAPTOMYCIN			S	<=0.5	
AMOX/K CLAV'ATE			R	<=4/2	
CEFTRIAXONE			R	<=8	
CIPROFLOXACIN			S	<=1	
CLINDAMYCIN			S	<=0.5	
ERYTHROMYCIN			R	>4	
GENTAMICIN			S	<=4	
OXACILLIN			R	>2	
RIFAMPIN			S	<=1	
SYNERCID			S	<=0.5	
TETRACYCLINE			S	<=4	
TRIMETH/SULFA			R	>2/38	
VANCOMYCIN			S	2	
LEVOFLOXACIN			S	<=1	
LINEZOLID			S	2	

RUN DATE: 05/24/16

RUN TIME: 1143

RUN USER: (b)(6)

(b)(6)

LAB *LIVE*

PAGE 2

*** PATIENT CARE INQUIRY - LAB ***

PCI User: (b)(6)

Lab Database: LAB (b)(6)

Name: (b)(6)

Sex: M Attend Dr:

Status: DIS IN

Location: G 5B

G.549-01

Specimen: (b)(6)

Collected: 09/18/15-0848 Status: COMP

Req#: 03560139

Received: 09/18/15-1207 Source: TSMRADP

Sp Desc: FLUID

Subm Dr:

Ordered: WOUND CULTURE

Comments: CONSERVATION

Procedure	Result	Verified	Site
-----------	--------	----------	------

WOUND CULTURE **Final** (continued)

S = Susceptible I = Intermediate

NS = Nonsusceptible

R = Resistant

R* = Predicted resistant interpretation

EBL? = Suspected ESBL

ESBL = Confirmed Extended Spectrum Beta-Lactamase

N/R = NOT REPORTED

BLAC = BETA LACTAMASE POSITIVE

COST = COST CODE

TFG = THYMIDINE DEPENDENT STRAIN

MIC = MCG/ML (MG/L)

BLANK = DATA NOT AVAILABLE, OR
DRUG NOT ADVISABLE/TESTED

A) USE MAXIMUM DOSES OF DRUGS WITH AN AMINOGLYCOSIDE FOR
P. AERUGINOSA IN PATIENTS WITH GRANULOCYTOPENIA OR SERIOUS
INFECTIONS.

B) BREAKPOINTS BASED ON PARENTERAL DOSE. FOR CEFUROXIME PO
USE <8=S, 8-16=I, >16=R

C) FOR STREPTOCOCCI AND NON-BETA LACTAMASE PRODUCING
ENTEROCOCCI REFER TO PENICILLIN INTERPRETATION

D) NITROFURANTOIN IS CONTRAINDICATED IN PATIENTS WITH
CrCl<60 mL/min.

E) IF KPC CONFIRMED, THIS ISOLATE DEMONSTRATES
CARBAPENEMASE PRODUCTION. THE CLINICAL EFFICACY OF THE
CARBAPENEMS HAS NOT BEEN ESTABLISHED FOR TREATING
INFECTIONS CAUSED BY Enterobacteriaceae THAT TEST
CARBAPENEM SUSCEPTIBILITY (eg. MIC ertapenem < OR = 2
ug/mL, imipenem < or = 4 ug/mL, AND/OR meropenem < or = 4
ug/mL) BUT DEMONSTRATE CARBAPENEMASE PRODUCTION in
vitro.

---INTERPRETATIONS BASED ON APPROXIMATE ADULT ATTAINABLE
SYSTEMIC/URINE LEVELS. DOSAGES ARE ONLY GUIDELINES;
CONSIDER WEIGHT, ACUITY, AND RENAL/HEPATIC FUNCTION

WHEN DETERMINING THERAPEUTIC DOSE. URINE INTERPRETATIONS ARE
FOR LOWER UTI ONLY.

RUN DATE: 05/24/16
 RUN TIME: 1343
 RUN USER: (b)(6)

(b)(6) LAB *LIVE*
 *** PATIENT CARE INQUIRY - LAB ***
 PCI User: (b)(6) Lab Database: LAB (b)(6)

PAGE 3

Name		Sex: M Attend D	
(b)(6)	Status: DIS IN	Location: G.5B	G 549-01
Specimen: (b)(6)			
Collected: 09/18/15-0848		Status: COMP	Req#: 03560139
Received: 09/18/15-1207		Source: LUMBAR	Sp Desc: FLUID
Subm Dr:			
Ordered: WOUND CULTURE			
Comments: CONSERVATION			
Procedure	Result	Verified	Site
WOUND CULTURE	Final (continued)	-	
INTERPRETATIONS BASED ON NCCLS M100-S12 JANUARY 2011			

RUN DATE: 05/24/16
 RUN TIME: 1343
 RUN USER: (b)(6)

(b)(6) LAB *LIVE*
 *** PATIENT CARE INQUIRY - LAB ***
 PCI User: (b)(6) Lab Database: LAB. (b)(6)

PAGE 2

Name: (b)(6)		Sex: M Attend Dr:	Status: DIS IN	Location: G.5B	G 549-01
Specimen: (b)(6)	Collected: 09/18/15-1345	Status: COMP	Req#: 03560391		
	Received: 09/18/15-1431	Source: LUMBAR	Sp Desc: OTHER		
Subm Dr:					
Ordered: ANAER CULTURE, AEROBIC CULT					
Comments: LUMBAR WOUND FROM SURGERY					
SAMPLE: SWAB					
Procedure	Result	Verified	Site		
AEROBIC CULTURE Final (continued) S = Susceptible I = Intermediate NS = Nonsusceptible R = Resistant R* = Predicted resistant interpretation EBL? = Suspected ESBL ESBL = Confirmed Extended Spectrum Beta-Lactamase N/R = NOT REPORTED BLAC = BETA LACTAMASE POSITIVE COST = COST CODE TFG = THYMIDINE DEPENDENT STRAIN MIC = MCG/ML (MG/L) BLANK = DATA NOT AVAILABLE, OR DRUG NOT ADVISABLE/TESTED A) USE MAXIMUM DOSES OF DRUGS WITH AN AMINOGLYCOSIDE FOR P. AERUGINOSA IN PATIENTS WITH GRANULOCYTOPENIA OR SERIOUS INFECTIONS. B) BREAKPOINTS BASED ON PARENTERAL DOSE. FOR CEFUROXIME PO USE <8=S, 8-16=I, >16=R C) FOR STREPTOCOCCI AND NON-BETA LACTAMASE PRODUCING ENTEROCOCCI REFER TO PENICILLIN INTERPRETATION D) NITROFURANTOIN IS CONTRAINDICATED IN PATIENTS WITH CrCl<60 mL/min. E) IF KPC CONFIRMED, THIS ISOLATE DEMONSTRATES CARBAPENEMASE PRODUCTION. THE CLINICAL EFFICACY OF THE CARBAPENEMS HAS NOT BEEN ESTABLISHED FOR TREATING INFECTIONS CAUSED BY Enterobacteriaceae THAT TEST CARBAPENEM SUSCEPTIBILITY (eg. MIC ertapenem < OR = 2 ug/mL, imipenem < or = 4 ug/mL, AND/OR meropenem < or = 4 ug/mL) BUT DEMONSTRATE CARBAPENEMASE PRODUCTION in vitro. ----- ---INTERPRETATIONS BASED ON APPROXIMATE ADULT ATTAINABLE SYSTEMIC/URINE LEVELS. DOSAGES ARE ONLY GUIDELINES; CONSIDER WEIGHT, ACUITY, AND RENAL/HEPATIC FUNCTION WHEN DETERMINING THERAPEUTIC DOSE. URINE INTERPRETATIONS ARE					

RUN DATE: 05/24/16

RUN TIME: 1343

RUN USER: (b)(6)

(b)(6)

LAB *LIVE*

PAGE 1

*** PATIENT CARE INQUIRY - LAB ***

PCI User: (b)(6) Lab Database: LAB. (b)(6)

Name:

(b)(6)

Sex: M Attend Dr:

Status: DIS IN

Location: G.5B

G.549-01

Specimen: (b)(6)

Collected: 09/18/15-1345 Status: COMP

Req#: 03560391

Received: 09/18/15-1431 Source: LUMBAR

Sp Desc: OTHER

Subm Dr:

Ordered: ANAER CULTURE, AEROBIC CULT

Comments: LUMBAR WOUND FROM SURGERY

SAMPLE: SWAB

Procedure

Result

Verified

Site

ANAEROBIC CULTURE Final

NO ANAEROBES ISOLATED 10 DAYS

09/28/15-0949

AEROBIC CULTURE Final

Organism 1

STAPH EPIDERMIDIS, METH RESIST

09/20/15-1219

QUANTITATION:

FEW COLONIES

1 STAPH EPIDERMIDIS, METH RESIST

ROUTE DOSE

INTERP

M.I.C.

COST

AMP/SULBACTAM

R

<=8/4

DAPTOMYCIN

S

<=0.5

AMOX/K CLAV'ATE

R

<=4/2

CEFTRIAXONE

R

<=8

CIPROFLOXACIN

S

<=1

CLINDAMYCIN

S

<=0.5

ERYTHROMYCIN

R

>4

GENTAMICIN

S

<=4

OXACILLIN

R

>2

RIFAMPIN

S

<=1

SYNERCID

S

<=0.5

TETRACYCLINE

S

<=4

TRIMETH/SULFA

R

>2/38

VANCOMYCIN

S

2

LEVOFLOXACIN

S

<=1

LINEZOLID

S

2

RUN DATE: 05/24/16

(b)(6)

LAB *LIVE*

PAGE 3

RUN TIME: 1247

*** PATIENT CARE INQUIRY - LAB ***

RUN USER: (b)(6)

PCI User: (b)(6)

Lab Database: LAB (b)(6)

Name: (b)(6)		Sex: M Attend Dr:	
Status: DIS IN		Location: G.5B G.549-01	
Specimen: (b)(6)	Collected: 09/18/15-1345	Status: COMP	Req#: 03560391
	Received: 09/18/15-1431	Source: LUMBAR	Sp Desc: OTHER
	Subm Dr:		
Ordered: ANAER CULTURE, AEROBIC CULT			
Comments: LUMBAR WOUND FROM SURGERY			
SAMPLE: SWAB			
Procedure	Result	Verified	Site
AEROBIC CULTURE	Final (continued)	-	
FOR LOWER UTI ONLY.			
INTERPRETATIONS BASED ON NCCLS M100-S12 JANUARY 2011			

U.S. Department of Health and Human Services

Voluntary Health Professional Report

Form Approved UMB No. 0010-0281 Expires 12/31/2011
See Only statement on reverse.**MEDWATCH**The FDA Safety Information and
Adverse Event Reporting ProgramFor VOLUNTARY reporting of
adverse events, product problems and
product use errors

FDA USE ONLY	
Trace unit sequence #	62234

A. PATIENT INFORMATION			
1. Patient Identifier (b)(6)	2. Age at Time of Event or Date of Birth: 7 Yr 18	3. Sex: <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight: 72.6 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	
Check all that apply: <input checked="" type="checkbox"/> Adverse Event <input type="checkbox"/> Product Problem (e.g., defects/malfunctions) <input checked="" type="checkbox"/> Product Use Error <input type="checkbox"/> Problem with Different Manufacturer of Same Medicine	
2. Outcomes Attributed to Adverse Event (Check all that apply) <input type="checkbox"/> Death (mm/dd/yyyy) <input type="checkbox"/> Life-threatening <input checked="" type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Congenital Anomaly/Birth Defect <input type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)	
3. Date of Event (mm/dd/yyyy) 07/10/2015	4. Date of this Report (mm/dd/yyyy) 07/20/2015

5. Describe Event, Problem or Product Use Error	
See additional page(s) for complete text.	

6. Relevant Tests/Laboratory Data, Including Dates	
See additional page(s) for complete text.	

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)	

C. PRODUCT AVAILABILITY	
Product Available for Evaluation? (Do not send product to FDA) <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on: mm/dd/yyyy	

D. SUSPECT PRODUCT(S)	
1. Name, Strength, Manufacturer (from product label) #1 Name: AlphaGut Strength: 1.0 ml Manufacturer: Aterinco, Inc.	
#2 Name: Strength: Manufacturer:	

2. Dose or Amount		Frequency	Route
#1			
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)		5. Event Abated After Use Stopped or Does Reduced?	
#1	08/26/2015 -	#1	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2		#2	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

4. Diagnosis or Reason for Use (Indication)		6. Event Reappeared After Reintroduction?	
#1	stomach pain	#1	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply
#2		#2	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

7. Expiration Date		8. NDC # or Unique ID	
#1		#1	
#2		#2	

E. SUSPECT MEDICAL DEVICE	
1. Brand Name	
2. Common Device Name	
3. Manufacturer Name, City and State	
Model #	Lot #
Serial #	Expiration Date (mm/dd/yyyy)
Other #	Other #
Implanted Give Date (mm/dd/yyyy)	If Expired, Give Date (mm/dd/yyyy)
This is a Single-use Device that was Reprocessed and Reused on a Patient? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
9. If Yes to Item No. 8 Enter Name and Address of Reprocessor	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS	
Product names and therapy dates (exclude treatment of event)	

G. REPORTER (See confidentiality section on back)	
1. Name and Address Name: (b)(6) Address: City: State: ZIP:	
Phone # Email: (b)(6)	
2. Health Professional? 3. Occupation (b)(6)	
4. Also Reported to: <input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> User Facility <input checked="" type="checkbox"/> Distributor/Importer	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: <input type="checkbox"/>	

FORM FDA 3500 (1/08)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

AEP 3297

030334

B.5. Describe Event or Problem (continued)

Patient had spinal fusion surgery with AlphaGens and MDC implanted on 8/24/15. 9/5/15 onset of pain at incision site. Returned to surgery for exploration of surgical wound.

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

9/5/15 Gram stain for WBC, no organisms seen, culture was no growth after 48 hours.

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, ethnicity, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

RUN DATE: 05/24/16

(b)(6)

LAB *LIVE*

PAGE 1

RUN TIME: 1345

*** PATIENT CARE INQUIRY - LAB ***

RUN USER: (b)(6)

PCI User: (b)(6) Lab Database: LAB (b)(6)

Name: (b)(6)	DOB: (b)(6)	Sex: F	Attend Dr: (b)(6)
Acct#: (b)(6)	Status: DEP SDC	Location: G.SD	
Specimen: (b)(6) Collected: 09/15/15-UNK Status: COMP Req#: 03558322 Received: 09/15/15-1953 Source: BACK Sp Desc: INCISION Subm Dr: (b)(6)			
Ordered: GRAM STAIN, ANAER CULTURE, AEROBIC CULT Comments: LUMBER WOUND DRAINAGE			
Procedure	Result	Verified	Site
GRAM STAIN Final	RARE WBC NO ORGANISMS OBSERVED	09/16/15-1320	
GRAM STAIN:			
ANAEROBIC CULTURE Final		09/25/15-1043	
NO ANAEROBES ISOLATED 10 DAYS			
AEROBIC CULTURE Final		09/25/15-0810	
NO GROWTH 10 DAYS			

RUN DATE: 05/24/16
 RUN TIME: 1346
 RUN USER: (b)(6)

(b)(6) LAB *LIVE*
 *** PATIENT CARE INQUIRY - LAB ***
 PCI User: (b)(6) Lab Database: LAB (b)(6)

PAGE 1

Name: (b)(6)	Sex: F	Attend Dr: (b)(6)
(b)(6)	Status: DEP SDC	Location: G.SD
Specimen: (b)(6)	Collected: 09/15/15-UNK	Status: COMP
	Received: 09/15/15-1953	Source: BACK
	Subm Dr: (b)(6)	
Ordered: FUNGUS	Req#: 03558322	Sp Desc: INCISION
Comments: LUMBER WOUND DRAINAGE		
Procedure	Result	Verified
FUNGUS CULTURE	Final	10/14/15-1316
NO GROWTH AFTER 4 WEEKS		

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of
adverse events, product problems and
product use errors

FDA USE ONLY

**Tring: A New
Acquaintance**

620332

A. PATIENT INFORMATION			
1. Patient Name (b)(6)	2. Age at Time of Event or Date of Birth: (b)(6)	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight or 54.1 lb
In confidence			
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR			
Check all that apply:			
1. <input checked="" type="checkbox"/> Adverse Event <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)			
<input checked="" type="checkbox"/> Product Use Error <input type="checkbox"/> Problem with Different Manufacturer of Same Medicine			
2. Outcomes Attributed to Adverse Event (Check all that apply)			
<input type="checkbox"/> Death: (mm/dd/yyyy)			
<input type="checkbox"/> Life-threatening <input type="checkbox"/> Disability or Permanent Damage			
<input checked="" type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Congenital Anomaly/Birth Defect			
<input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)			
3. Date of Event (mm/dd/yyyy) 09/23/15		4. Date of this Report (mm/dd/yyyy) 06/01/2015	
5. Describe Event, Problem or Product Use Error			
See additional page(s) for complete text.			
6. Relevant Tests/Laboratory Data, including Dates			
See additional page(s) for complete text.			
7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)			
See additional page(s) for complete text.			
C. PRODUCT AVAILABILITY			
Product Available for Evaluation? (Do not send product to FDA)			
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on (mm/dd/yyyy)			
D. SUSPECT PRODUCT(S)			
1. Name, Strength, Manufacturer (from product label)			
#1 Name: Alphagel Strength: 1.0 mL Manufacturer: Astorinject			
#2 Name: Strength: Manufacturer:			
E. SUSPECT MEDICAL DEVICE			
1. Brand Name			
Common Device Name			
Manufacturer Name, City and State			
Model #			
Lot #			
Expiration Date (mm/dd/yyyy)			
Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other			
2. If Implanted, Give Date (mm/dd/yyyy)			
3. If Explanted, Give Date (mm/dd/yyyy)			
4. Is this a Single-use Device that was Reprocessed and Reused on a Patient? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
5. If Yes to Item No. 4, Enter Name and Address of Reprocessor			
F. OTHER (CONCOMITANT) MEDICAL PRODUCTS			
Product names and therapy dates (include treatment or event)			
G. REPORTER (See confidentiality section on back)			
1. Name and Address			
Name: (b)(6)			
Address: (b)(6)			
City: (b)(6) State: (b)(6) ZIP: (b)(6)			
Phone #: (b)(6) E-mail: (b)(6)			
2. Health Professional? <input type="checkbox"/> 3. Occupation			
4. Also Reported to: <input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> User Facility <input checked="" type="checkbox"/> Distributor/Importer			
5. If you do NOT want your identity disclosed to this manufacturer, place an "X" in this box: <input type="checkbox"/>			

620333

B.5. Describe Event or Problem (continued)

patient had lumbar fusion surgery on 9/16/15. Had increased serosanguinous drainage at incision site with spike in temperature on 9/21/15. Returned to surgery on 9/21/15 for I&D. Fluid collected during that surgery is culture positive. Initial IFO stated packing was sterile, then IFO changed and said only the contents of the vial are sterile.

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

9/21/15 back: gram variable and Propionibacterium acnes 9/22/15 gram variable 9/22/15 Lumbar wound; gram variable bacteria were identified as Mycoplasma hominis

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

RUN DATE: 05/24/16

(b)(6)

LAB *LIVE*

PAGE 1

RUN TIME: 1340

*** PATIENT CARE INQUIRY - LAB ***

RUN USER: (b)(6)

PCI User: (b)(6)

Lab Database: LAB, (b)(6)

(b)(6)		-ex:M Attend Dr: "	
Status: DIS IN		Location: G.6A	G.624-01

Specimen: (b)(6) Collected: 09/22/15-1020 Status: COMP Req#: 03562503
 Received: 09/22/15-1026 Source: LUMBAR Sp Desc: OTHER
 Subm Dr:

Ordered: GRAM STAIN, ANAER CULTURE, AEROBIC CULT
 Comments: INFERIOR LUMBAR WOUND [POST LAVAGE]

HOLD 10 DAYS PER DR (b)(6)

Results CALLED to and READ back by DR (b)(6) on
 10/16/15 0720 by (b)(6)

Procedure	Result	Verified	Site
<u>GRAM STAIN</u> <u>Final</u> GRAM STAIN:	RARE WBC'S NO ORGANISMS OBSERVED	09/22/15-1525	
<u>ANAEROBIC CULTURE</u> <u>Final</u> NO ANAEROBES ISOLATED 10 DAYS		10/02/15-0958	
<u>AEROBIC CULTURE</u> <u>Final</u> Organism 1 QUANTITATION: ISOLATE COMMENT: ISOLATE COMMENT 2:	<u>MYCOPLASMA HOMINIS</u> MODERATE GROWTH IDENTIFIED BY FOCUS DIAGNOSTIC VIA QUEST SENSITIVITY NOT ROUTINELY PERFORMED FOR THIS ORGANISM	10/18/15-0709	

RUN DATE: 05/24/16
 RUN TIME: 1340
 RUN USER: (b)(6)

(b)(6) LAB *LIVE*
 *** PATIENT CARE INQUIRY - LAB ***
 PCI User: (b)(6) Lab Database: LAB (b)(6)

PAGE 1

(b)(6)		Fax: M Attend Dr:	
Status: DIS IN		Location: G.6A G 624-01	
Specimen: (b)(6)	Collected: 09/22/15-1020	Status: COMP	Req#: 03562502
	Received: 09/22/15-1024	Source: LUMBAR	Sp Desc: OTHER
	Subm Dr:		
Ordered: GRAM STAIN, ANAER CULTURE, AEROBIC CULT			
Comments: CONSERVATION			
INFERIOR LUMBAR WOUND [PRE-LAVAGE]			
HOLD 10 DAYS PER DR (b)(6)			
Procedure	Result	Verified	Site
<u>GRAM STAIN</u> <u>Final</u> GRAM STAIN:	MANY WBC'S NO ORGANISMS OBSERVED	09/22/15-1525	
<u>ANAEROBIC CULTURE</u> <u>Final</u> NO ANAEROBES ISOLATED 10 DAYS		10/02/15-0955	
<u>AEROBIC CULTURE</u> <u>Final</u> Organism 1 QUANTITATION: ISOLATE COMMENT:	<u>GRAM VARIABLE RODS</u> HEAVY GROWTH SENT TO CCF 9/30 ORGANISM NON-VIABLE	10/09/15-1216	

RUN DATE: 05/24/16
 RUN TIME: 1340
 RUN USER: (b)(6)

(b)(6) LAB *LIVE*
 *** PATIENT CARE INQUIRY - LAB ***
 PCI User: (b)(6) Lab Database: LAB (b)(6)

PAGE 1

(b)(6)		Sex: M Attend Dr:		
Status: REG CLI		Location: G.LAB		
Specimen: (b)(6)	Collected: 09/21/15-UNK	Status: COMP	Req#: 03562178	
	Received: 09/21/15-2140	Source: BACK	Sp Desc: ABSCESS	
	Subm Dr:			
Ordered: GRAM STAIN, ANAER CULTURE, AEROBIC CULT				
Procedure	Result	Verified	Site	
GRAM STAIN Final		09/22/15-1202		
GRAM STAIN:	MANY WBC'S RARE GRAM POSITIVE ROD			
ANAEROBIC CULTURE Final		10/08/15-0718		
Organism 1	PROPIONIBACTERIUM ACNES			
QUANTITATION:	MODERATE GROWTH			
BETA LACTAMASE:	NEGATIVE			
ISOLATE COMMENT:	SENSITIVITIES PERFORMED AT QUEST			
1. PROPIONIBACTERIUM ACNES				
	ROUTE DOSE	INTERP	M.I.C. COST	
CEFOXITIN		S	<=16	
CLINDAMYCIN		S	<=2	
IMIPENEM	IV 500 MG IVPB Q6H	S	<=4	100.00
PENICILLIN		S	<=0.5	
PIP/TAZ		S	<=32	
METRONIDAZOLE		R	>32.0	
@PLEASE ADD APPROPRIATE CHARGES FOR WHAT WAS PERFORMED AT				
@REF LAB				
AEROBIC CULTURE Final		10/09/15-1218		
Organism 1	GRAM VARIABLE RODS			
QUANTITATION:	HEAVY GROWTH			
ISOLATE COMMENT:	SENT TO CCF 9/30. ORGANISM NON-VIABLE			



Derived from human amnion tissue

Contents

This package contains Human Cellular and Tissue Based Products (HCT/P) as defined by US FDA 21 CFR Part 1271.

Federal (USA) law restricts this product to sale by or on the order of a licensed physician.

The donated human tissue has been determined eligible for human transplantation according to the criteria outlined in the Donor Selection section. AlphaPATCH is packaged in a double peel pouch in an outer box. The inner pouch and tissue are terminally sterilized via gamma irradiation and may be placed directly into the sterile field. Included in the packaging are a Tracking Record and a set of patient labels.

Description

- AlphaPATCH is a biological wound covering derived from human amnion.
- AlphaPATCH is intended for single patient, one time use only.
- AlphaPATCH must be used immediately after opening or discarded.

Precautions

- Do not use AlphaPATCH if packaging is damaged.
- Once the outer pouch is opened, AlphaPATCH should be used as soon as possible.
- Do not sterilize, re-sterilize or autoclave product.
- As with any human tissue, the possibility of infectious agent transmission cannot be eliminated, although all screening and microbial tests were satisfactory for this donor.
- Do not use on patients with a history of drug reactions to Penicillin or Amphotericin B.

Donor Selection

The Medical Director of the recovery agency has determined that the donor of the tissue in this product is eligible to donate tissue for transplantation based on the following criteria:

- The results of the donor screening indicated that the donor was free from risk factors for and clinical evidence of infection due to relevant communicable disease agents and diseases; and
- The results of donor testing for the following relevant communicable disease agents are negative or non-reactive:
 - Human immunodeficiency virus type 1 and 2 (HIV-1 and HIV-2)
 - hepatitis B
 - hepatitis C
 - human T-lymphotropic virus type 1 and type 2 (HTLV-1 and HTLV-2)
 - syphilis

A donor's medical history and behavior risk assessment are obtained prior to donation. Discussions with physicians and/or the donor mother are conducted to identify circumstances that may lead to exclusion of the donor or donated tissue. The blood sample test results, donor medical history, behavior risk assessment, physical assessment and other records have been evaluated.

Recovery

Tissue recovery is performed by Birth Tissue Recovery, using aseptic techniques. At the time of recovery, medical records are collected and reviewed for donor eligibility.

Processing

Storage

It is the responsibility of the end user to maintain AlphaPATCH in its original packaging at room temperature until use. Product expiration is printed on the outside of the box.

Recommended Instructions

These instructions are only guidelines and are not intended to supersede protocols or professional judgment regarding patient care.

- Open box containing AlphaPATCH.
- Open the outer pouch and aseptically present the inner foil pouch to the sterile field.
- Open the inner clear peel pouch and retrieve AlphaPATCH.
- Place the tissue on the surgical area to act as a covering or to deliver therapeutic actions.

Tracking

Recipient record must be maintained for the purpose of tracking tissue post-transplant. The allograft ID number must be recorded in the operative record. The tracking record must be completed and mailed back to Amniotic Therapies. Patient labels are included in this package to aid in tracking.